

## Medical Product Safety Reporting

**Purpose:** This protocol describes the actions to be taken by all staff whenever a serious adverse effect is suspected from nutritional products, drugs, biologicals or medical devices. This includes internal, as well as external reporting to the Food and Drug Administration, using the FDA approved form (Form 3500A).

### Procedure:

1. The organization's Quality Coordinator subscribes to and monitors incoming FDA and MedWatch alerts for relevance and application to the organization.
2. As part of the organization's Medical Recall program, the organization adheres to the Safe Medical Device Reporting Act and determines any applicable equipment that is in the organization.
3. Once equipment is identified, a malfunction reporting process is followed.
4. All protocols are reviewed and updated annually, if needed.
5. A "serious adverse effect" is defined as a reaction to one of the above, or other designated items, which is life threatening, leads to death or the loss of function and requires medical, surgical or hospital intervention to avoid permanent damage.
6. Examples of defective or malfunctioning products include, but are not limited to, poor labeling, poor packaging, suspected integrity of the product or a malfunction.
7. Forms and additional reporting information are available from the Federal Food and Drug Administration. (Form 3500A- See Addendum C).
8. To contact the FDA call or write to:

MedWatch: The FDA Medical Products Reporting Program

U.S. Food and Drug Administration  
MedWatch Office  
5600 Fishers Lane, HFD-410  
Rockville, MD 20857

Phone: 301-827-7240  
Fax: 301-827-7241  
Toll Free: 1-800-FDA-0188